



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-Day Comment Request NIH Electronic Application System for Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402-2512 or E-mail your request, including your address to: NIH-CoC-Coordinator@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on December 17, 2021, page 71650 (FR 86 pages 71650-71651) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public

comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after February 28, 2023, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, REVISION, exp., date 02/28/2023, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: The current CoC system sends system communications and the approved Certificate to the Principal Investigator and the Institutional Official. The optional data fields will allow the requester to identify another person that receives CoC system communications and the approved Certificate. This request system provides one electronic form to be used by all non-NIH funded research organizations that request a discretionary Certificates of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of the Department of Health and Human Services (HHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of discretionary CoCs has been delegated to the OER in the NIH Office of the Director. NIH received 795 requests for CoCs from January 2020 through December 2020 and expects to receive approximately the same number of requests in subsequent years. The NIH has been

using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes six sections of information collected from research organizations. The information provided is used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC are issued a Certificate of Confidentiality. This system has increased efficiency and reduced burden for both requesters and NIH staff who currently process these requests. OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1193.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Life Scientists	795	1	90/60	1193
		795		1193

Dated: March 9, 2022.

Tara A. Schwetz,

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National Institutes of Health.

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